SMALL BUSINESS SOURCES SOUGHT NOTICE
Notice Number: HHS-NIH-NCI-SBSS-PCPSB-45009-45
Title: Preclinical PREVENT Cancer Program: Toxicology and Pharmacology

This is a Small Business Sources Sought notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) whether they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. The NAICS code for this acquisition is 541711 - All Other Professional, Scientific, and Technological Services, which has a size standard of $15,000,000.

Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. An organization that is not considered a small business under the applicable NAICS code should not submit a response to this notice.

Purpose and Objectives: Preclinical Pharmacology and Toxicology Studies project within the Chemopreventive Agent Development Research Group (CADRG), Division of Cancer Prevention (DCP), National Cancer Institute (NCI) is seeking capability statements from all eligible Small Businesses as stated above, under NAICS Code 541711 (Research and Development in Biotechnology) with a size standard of 500 employees.

The NCI, CADRG/DCP is seeking contractors who demonstrate the ability to conduct studies to support the preclinical development of chemopreventive agents.

This contract will support the conduct of toxicological and pharmacological evaluations of potential cancer preventive agents for Investigational New Drug (IND) applications to the Food and Drug Administration (FDA) for phase 0, 1-3 clinical studies, New Drug Applications (NDA) to the FDA, and to select appropriate first-in-human (FIH) doses. This contract shall require the Contractor to perform studies in four areas: genotoxicity testing; general toxicology in experimental animals; reproductive toxicology studies in rodents and rabbits; and, specialized studies.

1. **TASK AREA 1 – GENOTOXICITY TESTING.**
   Provide services to determine the homogeneity, concentration, and stability of the test substance/test substance mixture under the conditions of use.

2. **TASK AREA 2 – GENERAL TOXICOLOGY IN EXPERIMENTAL ANIMALS.**
   Provide services to conduct studies in animals (mice, rats, dogs, rabbits, guinea pigs, hamsters, monkeys, and/or other animals) to text toxicity or carcinogenicity of chemopreventive agents.

3. **TASK AREA 3 – REPRODUCTIVE TOXICITY STUDIES IN RODENTS AND RABBITS**.
   Provide services to conduct studies in mice rats rabbits and other species, when appropriate to test reproductive toxicity.

4. **TASK AREA 4 – SPECIALIZED STUDIES**.
   Provide services to conduct studies in animals to evaluate drug-specific mechanisms of toxicity.

5. **GENERAL PROCEDURES**
   Have standard procedures registrations and accreditations related to the following:
   A. Animal Facilities
   B. Good Laboratory Practices (GLP) Regulations
   C. Pathology
   D. Assay of Test Material and Formulations
   E. Other considerations – protocol modifications, quality assurance, and statistics

Project Requirements:
A copy of the draft Statement of Work (SOW) pertaining to this requirement, which is subject to revisions, is attached to this notice.

Anticipated Period of Performance:
DURATION: It is anticipated that the ordering period for this ID/IQ contract will be 36 months. Task Orders may extend beyond the 36 month contract period.

Capability Statement/Information Sought:
Respondents must be qualified and prepare a capability statement for all Task Areas in the Statement of Work.

The Capability Statement will be evaluated based on the information provided in relation to the project requirements and the current capability and capacity to:
1) perform the work in the Task Area (s) in the attached Draft Statement of Work; 2) staff education, training, experience, expertise and knowledge; 3) prior completed projects and Government contracts of similar nature; 4) corporate experience and management capability.

Instructions for Submission of Capability Statements:

1. **Information Submission Instructions:**
   Interested qualified small business organizations should submit a capability statement, not to exceed 15 total single-spaced pages, double sided (2 sides = 2 pages) using a 12 point font size at a minimum, that clearly details the firms' ability to perform and that addresses the specific requirements described above and the draft Statement of Work (SOW). Please provide your DUNS number, organization name, address, point of contact, including names, titles, addresses, telephone, fax numbers, email addresses, and size and type of business (e.g., 8(a), HUBZone, etc.) pursuant to the applicable NAICS code. Responses will be reviewed only by NIH personnel and will be held in a confidential manner.

2. **Number of Copies/Delivery Point:**
   All capability statements sent in response to this Small Business Sources Sought notice must be submitted electronically (via email) to Miguel Diaz, Contract Specialist at miguel.diaz@mail.nih.gov and Donna Perry-Lalley, Contracting Officer at perryd@mail.nih.gov either in MS Word, or Adobe Portable Document Format (PDF). The email subject line must specify HHS-NIH-NCI-SBSS-PCPSB-45009-45. Facsimile and telephone responses will not be accepted.

3. **Common Cut-off Date:**
   Electronically submitted capability statements are due no later than **Friday, August 8, 2014, 4:00PM EST**. **CAPABILITY STATEMENTS RECEIVED AFTER THAT DATE AND TIME WILL NOT BE CONSIDERED.**

DISCLAIMER AND IMPORTANT NOTES:

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.

CONFIDENTIALITY:

No proprietary, classified, confidential, or sensitive information should be included in your responses. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).